May 14, 2003

Gary Wentworth, Ph.D.
Vice President, R&D
The C.P. Hall Company
311 S. Wacker Drive
Suite 4700
Chicago, IL 60606

Dear Dr. Wentworth:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for N,N-Dimethylalkanamides posted on the ChemRTK HPV Challenge Program Web site on January 17, 2003. I commend The C.P. Hall Company for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that The C.P. Hall Company advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: C. Auer
A. Abramson
W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
N,N-Dimethylalkanamides Category

Summary OF EPA Comments

The sponsor, C. P. Hall Company, submitted a test plan and robust summaries to EPA for the N,N-dimethylalkanamide category dated December 20, 2002. EPA posted the submission on the ChemRTK HPV Challenge Web site on January 17, 2003. The category consists of N,N-dimethyloctanamide (CAS No. 1118-92-9) and N,N-dimethyldecanamide (CAS No. 14433-76-2).

EPA has reviewed this submission and has reached the following conclusions:

1. Category Justification. The category justification provided by the submitter is acceptable.

2. Physicochemical Properties and Environmental Fate. Adequate data are available for all endpoints, except biodegradation, for the purposes of the HPV Challenge Program. However, the submitter needs to provide the physicochemical properties and fugacity data provided in the test plan for CAS No. 14433-76-2 in robust summary format.

3. Health Effects. All SIDS-level endpoints have been addressed for the purposes of the HPV Challenge Program.

4. Ecological Effects. Adequate data are available for all endpoints for the purposes of the HPV Challenge Program.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the N,N-dimethylalkanamides Category Challenge Submission

Category Definition

The submitter proposed a category of two N,N-dimethyl aliphatic amides: N,N-dimethyloctanamide (CAS No. 1118-92-9) and N,N-dimethyldecanamide (CAS No. 14433-76-2). N,N-dimethyldecanamide is produced commercially in a purified form ($\geq$ 98%) as Hallcomid M-10. N,N-dimethyloctanamide is produced as a commercial mixture, Hallcomid M-8-10, containing 50-65% N,N-dimethyloctanamide, 37-50% of N,N-dimethyldecanamide, 0-5% N,N-dimethylhexanamide, and 0-2% N,N-dimethyldodecanamide. The definition is clear and unambiguous.

Category Justification

The submitter justifies the N,N-dimethylalkanamide category on the basis of the close structural similarity of the two sponsored compounds, differing only by two carbons in their alkyl chains. The commercial mixture, Hallcomid M-8-10, consists of these two chemicals and minor amounts of two others having six- and twelve-carbon chains. The data and technical discussion provided by the submitter support the category.

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility).

Adequate data are available for these endpoints for the purposes of the HPV Challenge Program. However, data in robust summary format were provided only for CAS No. 1118-92-9. The submitter needs to provide the data for CAS No. 14433-76-2 in robust summary format.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity).

Adequate data are available for photodegradation, stability in water, and transport and distribution (fugacity) for the purposes of the HPV Challenge Program. However, the submitter needs to provide the transport and distribution data for CAS No. 14433-76-2 in robust summary format.

Biodegradation. The submitter provided biodegradation in soil data. This study is comparable to OECD Guideline 304 A "Inherent Biodegradation in Soil." Neither the objective of 304A (to determine inherent biodegradability) nor the test matrix (soil) resemble those of a ready biodegradation test. For the purposes of the HPV Challenge Program, the submitter needs to provide ready biodegradation data following OECD TG 301.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity).

Adequate data are available for all SIDS-level endpoints for the purposes of the HPV Challenge Program.

Repeated-Dose Toxicity. There is a typographical error in section 4.4.2, paragraph 2 on page 11 of the test plan. According to the study title, the dog gavage study by Vliegen (1996) was conducted on Hallcomid-M-8-10 and not Hallcomid-M-10.

Ecological Effects (fish, invertebrates, and algae).

Adequate data are available for the acute fish, aquatic invertebrate and algal toxicity endpoints for the purposes of the HPV Challenge Program.

Specific Comments on the Robust Summaries

Health Effects.

Acute Toxicity. The submitter needs to clarify the high dose level for the acute oral toxicity study in rats exposed to the mixture Hallcomid M-8-10 by gavage (ref. 21). Because the density of Hallcomid M-8-10 is reported to be 0.8835 and not 1.0, 5.0 **ml**/kg is not equal to 5.0 **g**/kg.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.